JUN 0 6 2014

2 510(k) Summary

I. Applicant Information

Date Prepared:	June 05, 2014
Submitter:	Medtronic, Inc.
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Alternate Contact	Donna Saito Sr. Regulatory Affairs Manager Medtronic, Inc. Phone: (949)-399-1675 Fax: (949) 553 8983 Email: donna.y.saito@medtronic.com

II. Device Name and Classification

Trade Name:	Temporary Pacemaker Electrode
Common Name:	Temporary Pacing Lead
Establishment Registration Number	2025587
Product Classification:	Class II 21 CFR 870.3680(a)
Product Code:	LDF

Predicate Devices	Model	Product Name
K012454	6491	Unipolar Pediatric Temporary Pacing Lead
K012458	6492	Unipolar Temporary Atrial Pacing Lead
K012459	6494	Unipolar Temporary Myocardial Pacing Wire
K012460	6495	Bipolar Temporary Myocardial Pacing Lead
K012452	6500	Unipolar Temporary Myocardial Pacing Lead

III. Indications for Use and Device Description

The Streamline[1]™ Temporary Pacing Leads are indicated for temporary atrial, or atrial and ventricular pacing and sensing for a contemplated implant duration of 7 day or less. The devices are supplied sterile and intended for single use only. The following are the specific device descriptions for each Streamline™ Temporary Pacing Lead model.

Model	Device Description
6491	The Model 6491 Unipolar Pediatric Temporary Pacing Lead consists of an electrode (1) and an insulated multi-filament conductor (2) which are crimped together (see **Figure 1**). A blue monofilament (3) proximally coiled for fixation of the lead is attached to the electrode and terminates distally in an atraumatic myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. To remove the pacing lead, gentle traction should be applied. No part of the lead remains in the body.
6492	The Model 6492 Unipolar Temporary Atrial Pacing Lead consists of an electrode (1) and an insulated multi-filament conductor (2) which are crimped together (see **Figure 2**). A blue monofilament (3) proximally coiled for fixation of the lead is attached to the electrode and terminates distally in an atraumatic myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. To remove the pacing lead, gentle traction should be applied. No part of the lead remains in the body.
6494	The Model 6494 Unipolar Temporary Myocardial Pacing Wire consists of an insulated multi-filament wire (1) (see **Figure 3**). One end of this wire has been stripped to have an electrode surface (2). This surface area can partly or completely be used as an electrode. The stripped end terminates distally in an atraumatic myocardial curved needle (3). An atraumatic chest needle (4) at the proximal end of the conductor wire permits running the pacing wire to exit through the chest wall. To remove the pacing wire, gentle traction should be applied. No part of the wire remains in the body.
6495	The Model 6495 Bipolar Temporary Myocardial Pacing Lead consists of an insulated multi-filament lead (see **Figure 4**) which contains a distal, discrete, ring electrode (1), a discrete, tip

[1] The trademark name Streamline™ mentioned throughout the document represents the heartwire product family Models; 6491, 6492, 6494, 6495, and 6500.

Model	Device Description
	electrode (2); and a coaxial conductor lead body (3). Each discrete electrode is crimped onto a conductor and terminates in an atraumatic, myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. Terminated on the back of the chest needle are two breakaway connector pins (6). To remove the pacing lead, gentle traction should be applied. No part of the lead remains in the body.
6500	The Model 6500 Unipolar Temporary Myocardial Pacing Lead consists of an electrode (1) and an insulated multi-filament conductor (2) which are crimped together (see **Figure 5**). A blue monofilament (3) proximally coiled for fixation of the lead is attached to the electrode and terminates distally in an atraumatic myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. To remove the pacing lead, gentle traction should be applied. No part of the lead remains in the body, except the silicone rubber disc (6) in case of atrial application.

IV. Comparison to Predicate Devices

A comparison of the modified product to the current marketed predicate products indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials

The differences between the modified products to the current marketed predicate devices are as follows:

- The pin protector is visually different and manufactured with a ridged material
- Aseptic presentation of the device; instead of a double pouch sterile barrier there is only a single pouch sterile barrier
- Shrink wrap will be removed and the shelf carton opening mechanism was changed
- Shelf Life reduction from 4 years to 2 years

V. Conclusion

Based upon the available testing, the modifications to the Streamline™ Temporary Pacing Leads do not affect the intended use of the devices or alter the fundamental scientific technology of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Medtronic, Inc.
% Debra Taitague
Regulatory Affairs Specialist
1851 East Deere Ave.
Santa Ana, California 92705

Re: K140972
Trade/Device Name: Streamline™ Heartwires Temporary Pacing Leads
Regulation Number: 21 CFR 870.3680(a)
Regulation Name: Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: May 6, 2014
Received: May 8, 2014

Dear Ms. Taitague,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

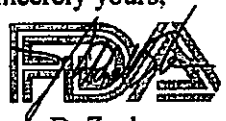
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1 Indications for Use

The following are the Indications for Use for each model of Streamline™ Temporary Pacing Leads:

- 6491
- 6492
- 6494
- 6495
- 6500

Indications for Use

510(k) Number (if known): K140972

Device Name: Model 6491 Unipolar Pediatric Temporary Pacing Lead

Indications for Use:

The Model 6491 Unipolar Pediatric Temporary Pacing Lead is designed for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): K140972

Device Name: Model 6492 Unipolar Temporary Atrial Pacing Lead

Indications for Use:

The Model 6492 Unipolar Temporary Atrial Pacing Lead is designed for temporary atrial pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): K140972

Device Name: Model 6494 Unipolar Temporary Myocardial Pacing Wire

Indications for Use:

The Model 6494 Unipolar Temporary Myocardial Pacing Wire is designed for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) 21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): K140972

Device Name: Model 6495 Bipolar Temporary Myocardial Pacing Lead

Indications for Use:

The Model 6495 Bipolar Temporary Myocardial Pacing Lead is designed for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): K140972

Device Name: Model 6500 Unipolar Temporary Myocardial Pacing Lead

Indications for Use:

The Model 6500 Unipolar Temporary Myocardial Pacing Lead is designed for temporary pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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